

HUMAN SUBJECTS WORKING GROUP MEETING AGENDA

**Sheraton
Boston, MA
Saturday, December 1, 2007
Room: Hampton**

Time	Presentation	Speakers
8:00 – 8:30 a.m.	Registration and Continental Breakfast	
8:30 – 8:45 a.m.	Welcome – Introductions	All
8:45 – 9:15 a.m.	Update - DOE - NNSA and Human Subjects	Speakers: Peter Kirchner, U.S. Department of Energy, Office of Science, SC-23.2 John Ordaz, National Nuclear Security Administration
9:15 – 10:15 a.m.	When is it “Human Subjects Research?” Moderator: Peter Kirchner, DOE-SC-23.2 Abstract: This presentation will discuss the applicability of the HHS regulations for the protection of human subjects to social behavioral research projects.	Speaker: Paul Andreason, Office of Human Research Protections, HHS
10:15 – 10:45 a.m.	Accreditation – Process, Review, Approval Moderator: Terry Reser, Sandia Abstract: The Ins and Outs, Ups and Downs of Accreditation.	Speaker: Sherry Davis, Pacific Northwest National Laboratory
10:45 – 11:00 a.m.	BREAK	
11:00 – 12:00 noon	Current Understanding of Radiation Exposure Effects on Humans: a Guide for IRB Risk Evaluations Moderator: Peter Kirchner, DOE-SC-23.2 Abstract: Ionizing radiation and nuclear medicine have served as valuable diagnostic tools employed in standard medical surveillance and in research protocols. This presentation will address the questions "What are the known and predicted health risks associated with the low radiation doses typically associated with medical exposures to humans?" and "How should that risk be disclosed by investigators to their patients and be evaluated by IRBs?"	Speaker: Evan Douple, National Academy of Sciences

Time	Presentation	Speakers
12:00 – 1:00 p.m.	Contemporary issues in Epidemiology, Surveillance and Disaster Response Research Moderator: Peter Kirchner, DOE-SC23.2 Abstract: <ul style="list-style-type: none"> • Epidemiology issues • Boundaries between research and practice • Research in disaster settings 	Speaker: Robert Levine, Yale University
1:00 – 2:15 p.m.	LUNCH Provided – Small Group Discussions	
2:15 – 3:15 p.m.	Challenges in the Oversight of Research with Decisionally-Impaired Subjects Moderator: Peter Kirchner, DOE-SC23.2	Speaker: David Strauss, SACHRP
3:15 – 3:45 p.m.	IRBNet – Electronic Management System for Managing Protocols Moderator: Betsy Ellis, ORISE	Speaker: Becky Hawkins, Oak Ridge Institute for Science and Education Andy Olmsted, IRBNet
3:45 – 4:00 p.m.	BREAK	
4:00 – 5:15 p.m.	Roundtable Discussion Moderator: Darcy Mallon, BNL <ul style="list-style-type: none"> - What is going on at your site? Main issues at your site - Offsite IRB - Adverse Events - Reporting Table Review - Status of Pending Legislation - Human Subjects Database, Poster, Brochure - Human Subjects Poster/Brochure - Other 	All Darcy Mallon, BNL Gail Van Gorp, ANL Debbie Motton, UC Merced John Knezovich, LLNL Ann-Marie Dake, LLNL Terry Reser, SANDIA Terry Reser, SANDIA Don Watkins, ORISE Denise Viator All
5:15 – 5:30 p.m.	Wrap Up	
6:30 p.m.	Meet in hotel lobby to connect with other members of the HSWG for dinner. Location TBD	